

FLEXUSPINE, INC.,	§	
	§	
<i>Plaintiff,</i>	§	
	§	
v.	§	Case No. 6:15-CV-201-JRG-KNM
	§	
GLOBUS MEDICAL, INC.,	§	
	§	
<i>Defendant.</i>	§	
	§	
	§	

On April 8, 2016, the Court issued an order construing the disputed claim terms of United States Patent Numbers 7,204,853 (“the ’853 Patent”), 7,316,714 (“the ’714 patent”), 7,909,869 (“the ’869 Patent”), 8,123,810 (“the ’810 Patent”), and 8,647,386 (“the ’386 Patent”) asserted in this suit by Plaintiff Flexuspine, Inc. (“Plaintiff”) against Defendant Globus Medical, Inc. (“Defendant”). During the Pretrial Conference held on July 7, 2016, the parties identified a dispute regarding the scope of the terms “configured to” and “configured such that.” The Court allowed the parties to file supplemental claim construction briefing. After considering the parties’ supplemental briefing (Doc. Nos. 151, 153, and 163), the Court issues this Supplemental Claim Construction Memorandum Opinion and Order, and **ADOPTS** the constructions set forth below.

I. BACKGROUND

The asserted patents relate to expandable intervertebral implants. The '853 and '714 Patents disclose device claims directed toward artificial spinal unit assemblies. The '810 Patent discloses an intervertebral implant with a “wedged” expansion member. The term “configured to” appears in claim 1 of the '853 Patent, claims 1 and 2 of the '714 Patent, and claim 17 of the '810 Patent. The term “configured such that” appears in claim 1 of the '714 Patent. Claim 1 of the '853 Patent is an exemplary claim and recites the following elements (disputed term in italics):

1. An intervertebral implant for a human spine, comprising:
 - an upper body comprising an inferior surface and a superior surface, wherein the superior surface of the upper body is *configured to* engage a first vertebra of the human spine;
 - a lower body comprising a superior surface and an inferior surface, wherein the inferior surface of the lower body is *configured to* engage a second vertebra of the human spine;
 - an insert *configured to* be positioned between the superior surface of the lower body and the inferior surface of the upper body before insertion of the intervertebral implant between the first vertebra and the second vertebra of the human spine; and
 - an expansion member *configured to* elevate the insert to increase a separation distance between the upper body and the lower body after insertion of the intervertebral implant in the human spine, and wherein a portion of the superior surface of the lower body is *configured to* inhibit backout of the expansion member from the intervertebral implant.

II. APPLICABLE LAW

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In claim construction, courts examine the patent’s intrinsic evidence to define the patented invention’s scope. *See id.*;

C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, a term's context in the asserted claim can be very instructive. *Id.* Other asserted or unasserted claims can also aid in determining the claim's meaning because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term's meaning. *Id.* For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id.* at 1314–15.

“[C]laims ‘must be read in view of the specification, of which they are a part.’” *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). “[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* (quoting *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is true because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor's lexicography governs. *Id.* Also, the specification may resolve ambiguous claim terms “where

the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone.” *Teleflex, Inc.*, 299 F.3d at 1325. But, “[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.” *Comark Commc’ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc., v. Lifescan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004) (“As in the case of the specification, a patent applicant may define a term in prosecuting a patent.”).

Although extrinsic evidence can be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert’s conclusory, unsupported assertions as to a term’s definition is entirely unhelpful to a court. *Id.* Generally, extrinsic evidence is “less reliable than the patent and its prosecution history in determining how to read claim terms.” *Id.*

III. CONSTRUCTION OF DISPUTED TERM

1. “configured to” and “configured such that”

<u>Disputed Term</u>	<u>Plaintiff’s Proposal</u>	<u>Defendant’s Proposal</u>
“configured to” / “configured such that” ¹	“constructed to operate without modification”	“designed to”

a) The Parties’ Positions

The parties dispute whether the term “configured to” means “constructed to operate without modification,” as Plaintiff proposes, or if it means “designed to,” as Defendant proposes. Plaintiff argues that the asserted claims are apparatus claims, and that infringement of the claims occurs when the accused apparatus “is used or is available for use.” (Doc. No. 151 at 2) (citing *Mass Engineered Design, Inc. v. Ergotron, Inc.*, 633 F. Supp. 2d 361, 378 (E.D. Tex. 2009)). According to Plaintiff, the appropriate interpretation of “configured to” is that the accused implant is actually constructed such that it is capable of operating in the manner specified by the asserted claims at any time, without modification. (*Id.* at 3.)

Plaintiff further argues that the specification describes how the structure of the preferred embodiment “operates to expand the implant from a contracted to an expanded state, and how it interacts within the human spine.” (*Id.*) According to Plaintiff, “[t]his suggests that the patentee contemplated that the components would be arranged and the implant would be constructed such that it is capable of, and actually does perform, a particular operation when used.” (*Id.*) Plaintiff further contends that a “precise arrangement of components to achieve the claimed operation (or a specific intent to arrange them or operate them in a certain way) is not required.” (*Id.*) Plaintiff also argues that the extrinsic evidence indicates that “configured” means “to set up for operation” or “to arrange or prepare (something) so that it can be used” (*Id.*) (citing Merriam-

¹ The order will generally discuss the term “configured to” with the understanding that the analysis applies equally to the term “configured such that.”

Webster's Collegiate Dictionary 241 (10th ed. 2001); Merriam-Webster's Learner's Dictionary, available at Merriam-Webster.com.)

Regarding Defendant's construction, Plaintiff argues that Defendant will contend that the accused products were not "configured to" have certain limitations asserted in the claims because Defendant did not intend them to have those limitations. (*Id.* at 5.) Plaintiff contends that "the designer's intention behind the design does not play any part in determining direct infringement of an apparatus claim." (*Id.*) Plaintiff further argues that "[a]ny construction that would infuse a requirement to prove the subjective intent of a designer into the infringement inquiry would confuse the scope of the claims and should be rejected." (*Id.*)

Plaintiff also contends that it "is not arguing that the [a]sserted [c]laims be read to cover implants that are 'configured to' operate in a certain manner because they are capable of being modified to operate" in such a fashion. (*Id.* at 6.) Plaintiff further contends that it is not arguing that the asserted claims "be read to cover implants that are merely capable of infringing only when used in a contraindicated manner that differs from its indicated use." (*Id.*) According to Plaintiff, the Court's construction "should reflect that the implant is constructed to operate in the manner further claimed in the remainder of the limitation." (*Id.*)

Defendant responds that courts have found that "configured to" does not mean "capable of," and instead requires that the component is intentionally designed to perform the claimed function.² (Doc. No. 153 at 2.) Defendant contends that Plaintiff "erroneously suggests that cases have held that 'configured to' can have the broad interpretation it advocates." (*Id.* at 4.) Defendant argues that "the asserted claims set forth certain required characteristics or

² The parties cite to a number of district court cases, both within the district and outside of the district. The Court appreciates the value of this persuasive authority, and was informed by the facts and disputes in each of the cited cases. The Court has fully considered the findings and conclusions of the cited cases in the light of the parties' arguments and the facts in this case.

components that perform certain functions.” (*Id.*) Defendant argues that the claims describe upper and lower bodies ‘configured to engage’ a first or second vertebra.” (*Id.*) According to Defendant, “[t]he patentees did not describe an intervertebral implant that is merely ‘capable of’ engaging a first and second vertebrae.” (*Id.*) Defendant further contends that Plaintiff’s “interpretation would render these limitations devoid of meaning because anything in the implant is capable of engaging the vertebrae.” (*Id.*)

Defendant also argues that “configured to elevate” in claim 1 of the ’853 Patent “cannot simply mean that the insert (or the entire implant) is ‘capable of’ elevating under some set of circumstances.” (*Id.*) Defendant contends that “‘configured to elevate’ indicates that the expansion member must be designed to elevate the insert to accomplish the specified objective of increasing a separation distance between the upper and lower bodies.” (*Id.*) According to Defendant, “[n]othing in the claim supports the broader interpretation that the expansion member is simply ‘capable of’ elevating the insert or that the insert is merely ‘capable of’ elevating as an unintended consequence of expansion.” (*Id.* at 5.)

Defendant further argues that “the phrase ‘a portion of the superior surface of the lower body is configured to inhibit backout’ must be construed to mean ‘a portion of the superior surface of the lower body is designed to inhibit backout.’” (*Id.*) Defendant contends that claim 1 of the ’714 Patent “requires the claimed intervertebral implant to be designed to allow articulation (or increased articulation) as the separation distance between the upper and lower bodies increases.” (*Id.*) Defendant argues that “[c]laim 1 is meaningless if the implant need only be ‘capable of’ articulation or increased articulation once the distance between the upper and lower bodies is increased.” (*Id.*)

Defendant also argues that the specification of the ’853 Patent “describes an expansion

member that is specifically designed to raise the insert—not simply that the expansion member . . . is ‘capable of’ raising the insert under some hypothetical set of circumstances.” (*Id.*) (’853 Patent at 5:21–25, 5:32–34). Defendant further argues that “[t]he specification also confirms that a portion of the superior surface of the lower body must be intentionally designed to inhibit backout.” (Doc. No. 153 at 6) (citing ’853 Patent at 9:38–40). Defendant also contends that “articulation (or increased articulation) is one of the ’714 Patent’s primary goals.” (Doc. No. 153 at 6) (citing ’714 Patent at 3:31–37). Defendant argues that the specification of the ’714 Patent “describes the articulation that results from an increase in the separation distance between the upper and lower bodies in terms of specific design.” (Doc. No. 153 at 6) (’714 Patent at 5:37–40). Defendant contends that the specification “show[s] that the claimed implant should be designed to allow articulation or increased articulation, not that it is merely ‘capable of’ doing so.” (Doc. No. 153 at 7.)

Defendant further contends that “[i]t is not enough for an implant to elevate or for an insert to elevate.” (*Id.* at 7.) Defendant argues that claim 1 “requires that the ‘expansion member’ be ‘configured to elevate the insert.’” (*Id.*) Defendant also argues that “mere inhibition of backout is not enough under claim 1 of the ’714 Patent.” (*Id.*) According to Defendant, “a portion of the superior surface of the lower body must be configured to inhibit backout of the expansion member.” (*Id.*) Defendant further argues that articulation or increased articulation must result from increasing the separation distance between the upper and lower bodies. (*Id.*) Defendant also contends that the dictionary definitions cited by Plaintiff “look back in time to the design process and require inquiry into how a device was ‘set up’ ‘arranged’ or ‘prepared’ to operate.” (*Id.*)

Defendant also argues that it is not attempting to impose “use” limitations on apparatus

claims. (*Id.* at 8) Defendant contends that it “seeks to impose ‘meaningful limits’ on the claims, which define the invention in terms of function, *e.g.*, ‘configured to elevate.’” (*Id.*) According to Defendant, “[t]he patentees elected to use the terms ‘configured to’ in their claims, and ‘designed to’ is the only construction that gives the claims’ structural language any meaning.” (*Id.*) Defendant contends that Plaintiff’s construction “reads out ‘configured to’ from the claim language.” (*Id.*) Defendant also argues that it “does not seek to impose a *mens rea* element on direct infringement.” (*Id.*) Defendant further contends that its construction “properly imposes meaning on the claims’ functional language and sets forth the attributes, *i.e.*, the metes and bounds, of the claimed implants.” (*Id.* at 9.)

Finally, Defendant argues that “[w]hether an accused device performs the claimed function ‘some of the time’ has no bearing on the threshold issue of whether the scope of the claims requires that an accused device be designed to perform the claimed function.” (*Id.* at 11.) Defendant contends that Plaintiff “may also argue that inhibiting of backout or articulation does in fact occur when implants are placed in the human body, and so the claim limitations at issue are met no matter what the Court’s construction is.” (*Id.*) According to Defendant, “[t]he question is what mechanism performs those functions under the claims and whether those mechanisms are designed with that function in mind.” (*Id.*)

Plaintiff replies that Defendant’s construction is improper because “the use of the term ‘designed’ introduces the subjective intent of the person or party doing the ‘designing.’” (Doc. No. 163 at 2.) Plaintiff argues that “[t]his goes too far and will result in a very high risk of misleading . . . the jury into believing that subjective intent to infringe is required.” (*Id.*) Plaintiff also argues that its construction “focuses on the operation of the device exactly as it is constructed.” (*Id.*) Plaintiff contends that it “specifically included ‘without modification’ in its

proposal to ensure that there are no issues of infringement based on any modifications to the device.” (*Id.*) Plaintiff also argues that its construction “requires that the device actually does perform the claimed function, as constructed, when . . . used in its intended environment between two vertebrae in the human spine.” (*Id.* at 2–3.)

Plaintiff further argues that whether “a device was ‘designed’ with subjective intent to perform a recited function is irrelevant to whether that device is ‘configured to’ perform it.” (*Id.* at 3.) Plaintiff contends that “[p]roducts can be, and often are, constructed such that they can perform a function without being subjectively designed to do so.” (*Id.*) According to Plaintiff, the accused devices are “either structured such that the expansion member is elevated, that backout of the expansion is inhibited, or that the expansion allows for articulation, or they are not.” (*Id.*)

For the following reasons, the terms “**configured to**” and “**configured such that**” should be given their plain and ordinary meaning.

b) Analysis

The term “configured to” appears in claim 1 of the ’853 Patent, claims 1 and 2 of the ’714 Patent, and claim 17 of the ’810 Patent. The term “configured such that” appears in claim 1 of the ’714 Patent. The terms are used consistently in the claims and are intended to have the same general meaning in each claim. As an initial matter, the Court rejects both parties’ constructions because the proposals are inconsistent with the intrinsic evidence. Although both sides downplay the intent of their respective constructions, the import of the constructions is clear. Specifically, Plaintiff argues that “configured to” only requires the implant to be “constructed such that [it] is *capable* of operating in the manner specified by the Asserted Claims.” (Doc. No. 151 at 3) (emphasis added). Likewise, Defendant argues that “configured to”

requires the component to be “*intentionally designed* to perform the claimed function.” (Doc. No. 153 at 2) (emphasis added).

With respect to Plaintiff’s construction, interpreting “configured to” as requiring only mere capability would eliminate any meaningful limits to the claims. *See, e.g., SIPCO, LLC v. Abb, Inc.*, Case No. 6:11-cv-48, 2012 U.S. Dist. LEXIS 106659, *29–33 (E.D. Tex. July 30, 2012). Here, the asserted claims set forth certain required characteristics or components that perform certain functions. For example, the claims describe upper and lower bodies “configured to engage” a first or second vertebra. The patentees did not describe an intervertebral implant that is merely “capable of” engaging a first and second vertebrae. Such an interpretation would render these limitations “devoid of meaning” because anything in the implant is capable of engaging the vertebrae. *Id.* at *32.

For the same reason, “configured to elevate” in claim 1 of the ’853 Patent requires more than an insert that is merely “capable of” elevating. Likewise, claim 1 of the ’714 Patent would be meaningless if the implant needed to only be “capable of” articulation or increased articulation. In sum, a “capable of” construction would eviscerate the claim’s limitation that the implant is configured to perform the function of allowing articulation or increased articulation through expansion.

The specification further confirms that “configured to” does not mean merely capable. The Summary of the Invention section in the ’853 Patent describes an expansion member that raises the insert, and not simply an expansion member that is “capable of” raising the insert. *See, e.g., ’853 Patent* at 5:21–24 (“The expandable joint insert is raised above the bottom of the channel by means of an expansion screw, an expansion plate, or other similar device”); ’853 Patent at 5:32–34 (“... the expandable joint is raised above the floor of the channel and lifts the

upper body above the lower body to the desired disc height.”). Likewise, the specification describes “a locking lip to ensure that the expansion plate is properly installed and to minimize the potential for dislocating expansion plate 82.” ’853 Patent at 9:38–40.

Similarly, the ’714 Patent states that one of its primary goals is articulation (or increased articulation) to “provide an anatomically correct range of motion.” ’714 Patent at 3:31–37. Accordingly, the specification describes the articulation that results from being flexed and extended. ’714 Patent at 5:40–43 (“As the artificial implant is flexed and extended, the convex superior surface of the expandable joint insert articulates with the concave inferior surface of the upper body.”). The figures of the ’714 Patent reinforce “articulation” as a functional requirement. *See, e.g.*, Figures 4a and 4b. These statements and figures show that the claimed implant requires more than merely “capable of” articulation or increased articulation.

Plaintiff appears to suggest that it is not arguing “mere capability,” but its construction and arguments indicate otherwise. For example, Plaintiff argues that “the patentee contemplated that the components would be arranged and the implant would be constructed such that it is *capable of*, and *actually does perform*, a particular operation when used.” (Doc. No. 151 at 3.) (emphasis added). Yet, Plaintiff’s construction does not include the words “actually does perform” or “actually configured” language. Accordingly, the Court rejects Plaintiff’s construction.

With respect to Defendant’s arguments, Defendant’s construction improperly confuses the scope of the claims by suggesting that the intent of a designer must be established to determine the bounds of the claim. As noted by Plaintiff, the asserted claims are apparatus claims, and the subjective intent of the designer does not expand or contract the claim’s scope. In other words, the infringement inquiry is based on the structure of the accused devices as claimed.

Furthermore, the Court agrees with Plaintiff that products can be constructed such that they perform a function without being subjectively designed to do so.

Defendant argues that it “does not seek to impose a *mens rea* element on direct infringement.” (Doc. No. 153 at 8.) Yet, Defendant also argues that “‘configured to’ does not mean ‘capable of,’ and instead requires that the component is ***intentionally designed*** to perform the claimed function.” (Doc. No. 153 at 2) (emphasis added). It is hard to understand how “intentionally designed” would not require determining the “intent” of the designer. Accordingly, the Court rejects Defendant’s construction.

In summary, the Court appreciates that the parties would like a construction that clearly establishes whether a product does or does not infringe. However, that is not the Court’s role in construing the disputed terms. *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (“[D]istrict courts are not (and should not be) required to construe every limitation present in a patent’s asserted claims.”). Instead, the Court is to give the disputed terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003). Here, the term “configured to” means that the apparatus performs the recited limitations when used as an intervertebral implant for a human spine. Indeed, Plaintiff appears to agree by arguing that its “construction requires that ***the device actually does perform the claimed function***, as constructed, when in use in its intended environment between two vertebrae in the human spine.” (Doc. No. 163 at 2–3) (emphasis added). As discussed, this requires proving more than mere capability, but less than proving that a device was “intentionally designed to perform the claimed function.” (Doc. No. 153 at 3.)

Having resolved the parties' claim construction dispute, whether an apparatus is "configured to" meet the claim limitations is a question of fact that is properly submitted to the jury. *See PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("[A]fter the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact."). Accordingly, the terms **"configured to"** and **"configured such that"** should be given their plain and ordinary meaning.

c) Court's Construction

In light of the evidence submitted by the parties, the terms **"configured to"** and **"configured such that"** will be given their plain and ordinary meaning. The Court's construction prohibits Defendant from arguing to the jury that the accused products do not infringe because they were not designed to perform the recited function. The Court's construction also prohibits Plaintiff from arguing to the jury that the accused products infringe because they are merely capable of performing the recited function. In summary, the Court's construction requires proving that the apparatus actually does perform the recited limitations when used as an intervertebral implant for a human spine.

IV. CONCLUSION

The Court adopts the above constructions. The parties are ordered to not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any part of this opinion, other than the definitions adopted by the Court, in the presence of the jury. However, the parties are reminded that the testimony of any witness is bound by the Court's reasoning in this order but any reference to

claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

So ORDERED and SIGNED this

Aug 5, 2016



K. NICOLE MITCHELL
UNITED STATES MAGISTRATE JUDGE